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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,691	02/06/2004	Vinod B. Shidham	128880.00002	7800

26710 7590 06/18/2007
QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE
SUITE 2040
MILWAUKEE, WI 53202-4497

EXAMINER

TOWA, RENE T

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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06/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/773,691

Applicant(s)

SHIDHAM ET AL.

Examiner

Rene Towa

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is responsive to an amendment filed April 18, 2007. Claims 40-58 are pending. Claims 1-39 are cancelled. New claims 40-58 have been added. No claim has been amended.

Claim Objections

2. The objection is withdrawn due to amendments.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 40-41, 43-44 and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries (US Patent No. 4,967,762) in view of Dann et al. (US Patent No. 2,840,075).

In regards to claims 40 and 47-49, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device comprising:

a hub 40 defining a specimen collection well 62 and mounting a needle 70 having a shaft with an open pointed tip; and

a sample passageway 64 extending from the pointed tip of the needle 70 to a segment inside the hub opening in spaced relation to a floor of the collection well 62 (see figs. 1-2); DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the hub 40 defines an opening 64 in the floor of the collection well 62 through which the needle shaft extends (see fig. 2); DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the

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proximal end of the needle 70 in part follows the contour of the collection well 62 (see fig. 2); DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the hub 40 includes an outer grip 52 (see figs. 1-2); DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the hub 40 has an open mouth 50 allowing access to the collection well 62 (see fig. 2).

In regards to claim 41, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the needle 70 defines the entire passageway 64 extending from the pointed tip to a contoured proximal end (see fig. 2).

In regards to claim 43, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the passageway 64 is defined in part by the needle 70 and in part by an internal channel in the hub 40 (see fig. 2).

In regards to claim 44, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the needle 70 has a straight proximal end disposed at an opening in the hub 40 defining an end of the channel (see fig. 2).

DeVries discloses an apparatus, as described above, that teaches all the limitations of the claims except DeVries does not teach a specimen passageway wherein a specimen can pass through the needle into the hub and be deposited in the collection well from above the floor. However, Dann et al. disclose an apparatus comprising a specimen passageway 30 wherein a specimen can pass through the needle 30 and be deposited in the collection well 28 from above the floor (see figs. 4-5). It would have been obvious to one of ordinary skill in the art at the time Applicant's

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invention was made to provide an apparatus similar to that of DeVries with a specimen passageway similar to that of Dann et al. in order to more visibly observe the passage of blood into the collection well (see Dann et al., column 1/line 66 to column 2/line 13; column 2/lines 65-68; column 3/lines 3-9, 14-16 & 33-39).

5. Claims 42 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devries ('762) in view of Dann et al. ('075) further in view of Dysarz (US Patent No. 6,589,209).

Devries as modified by Dann et al. discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except Devries as modified by Dann et al. does not teach a needle segment that extends along and opens about a lateral axis at an angle to a longitudinal axis. However, Dysarz discloses a needle aspiration device wherein the proximal end of the needle includes a segment that extends along and opens about a lateral axis at an angle to a longitudinal axis of the needle; wherein the lateral and longitudinal axes are essentially perpendicular (see fig. 21A). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a needle aspiration device with a needle segment similar Devries as modified by Dann et al. with a needle similar to that of Dysarz in order to provide the needle with a safer connection that would resist slippage thereof.

6. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Devries ('762) in view of Dann et al. ('075) further in view of Guerra ('432).

Devries as modified by Dann et al. discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except for an internal passage that does not pass through the collection floor. However, Guerra disclose an apparatus comprising a specimen passageway wherein a specimen can pass through the needle 18B and be deposited in the collection well 19 from above the floor; wherein the internal passage does not pass the collection well floor (see figs. 1-2). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an apparatus similar to that of DeVries with a specimen passageway similar to that of Guerra since such a modification would serve the same purpose of drawing a specimen into the collection well (see Guerra, column 3/lines 16-40).

7. Claims 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Dann et al. ('075) further in view of Ellingson et al. (US Patent No. 6,217,556).

In regards to claim 50, DeVries as modified by Dann et al. disclose a high specimen yielding anti-reflux needle aspiration biopsy device, comprising:

- a syringe including a barrel 20 and a piston 34 slidable within the barrel 20;

- a hub 40 and defining a specimen collection well 62; and

- a needle 70 mounted to the hub 40 having a shaft with an open pointed tip;

wherein at least one hub 40 and needle 70 define a passageway 64 extending from the needle tip to inside the hub opening to a floor of the collection well 62 (see DeVries, figs. 1-2).

In regards to claim 51, DeVries as modified by Dann et al. disclose a high specimen yielding anti-reflux needle aspiration biopsy device wherein the needle 70 defines the entire passageway extending from the pointed tip to a contoured proximal end (see figs. 1-2).

DeVries as modified by Dann et al. disclose a system, as described above, that teaches all the limitations of the claims except DeVries as modified by Dann et al. do not teach a valve for controlling an opening in the syringe barrel. However, Ellingson et al. disclose a valve 23 for controlling an opening in a syringe barrel 63 (see fig. 1) and a coupler 35 (see fig. 3A). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that a valve to that of DeVries as modified by Dann et al. with a valve similar to that of Ellingson et al. in order to control the flow of fluid (see Ellingson et al., column 3/lines 17-22).

8. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Dann et al. ('075) further in view of Ellingson et al. ('556) even further in view of Dysarz (US Patent No. 6,589,209).

DeVries as modified by Dann et al. and Ellingson et al. disclose a system, as described above, that teaches all the limitations of the claims except DeVries as modified by Dann et al. and Ellingson et al. does not teach a passageway that is defined in part by a needle and an internal channel in the hub. However, Dysarz discloses a system as follows:

However, Dysarz discloses a system wherein a passageway is defined in part by the needle 39 and in part by an internal channel 20 in the hub 48 (see figs. 1 & 18-19).

It would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Dann et al. and Ellingson et al. with a passageway similar to that of Dysarz since such a modification would serve the same purpose of drawing a specimen into the collection well. It has previously been held that merely changing aesthetic design is not patentable--See *In re Seid*, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

9. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Dann et al. ('075) further in view of Ellingson et al. ('556) even further in view of Banys et al. ('376).

In regards to claim 54, DeVries as modified by Dann et al. and Ellingson et al. disclose a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except DeVries as modified by Dann et al. and Ellingson et al. do not teach a piston lock. However, Banys et al. teach a piston lock 42 mounted to the syringe so as to hold the position of the piston relative to the barrel (see figs. 5-6). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a biopsy device similar to that of DeVries as modified by Dann et al. and Ellingson et al. with a piston lock similar to that of Banys et al. in order to hold the plunger in the fully inserted position within the syringe (see column 2/lines 63-65; column 4/lines 34-38).

10. Claims 50-51, and 55-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Dann et al. ('075) further in view of Markham (US Patent No. 4,549,554).

In regards to claim 50, DeVries as modified by Dann et al. disclose a high specimen yielding anti-reflux needle aspiration biopsy device, comprising:

- a syringe including a barrel 20 and a piston 34 slidable within the barrel 20;

- a hub 40 and defining a specimen collection well 62; and

- a needle 70 mounted to the hub 40 having a shaft with an open pointed tip;

wherein at least one hub 40 and needle 70 define a passageway 64 extending from the needle tip to inside the hub opening to a floor of the collection well 62 (see DeVries, figs. 1-2).

In regards to claim 51, DeVries as modified by Dann et al. disclose a high specimen yielding anti-reflux needle aspiration biopsy device wherein the needle 70 defines the entire passageway extending from the pointed tip to a contoured proximal end (see figs. 1-2).

In regards to claim 55, DeVries as modified by Dann et al. discloses a method as follows:

- inserting the needle 70 into a specimen sample site;

- communicating a vacuum to the needle 70;

- probing the specimen sample site with the needle 70 to collect specimens in the collection well of the hub 40;

- releasing the vacuum in the needle 70;

- withdrawing the needle 70 from the specimen sample site;

- separating the hub from the device; and

transferring specimens collected in the hub to an examination site (see DeVries, column 1/lines 55-72; column 2/lines 3-12; column 3/lines 1-3 & 8-14).

DeVries as modified by Dann et al. teach a system, as described above, that teaches all the limitations of the claims except DeVries as modified by Dann et al. does not teach creating a vacuum by closing a valve and pulling a piston. However, Markham teaches a method as follows:

In regards to claim 55, Markham discloses a method of needle aspiration biopsy using a device as recited in claim 50, comprising the steps of:

- creating a vacuum in the syringe 10;
- inserting the needle 36 into a specimen sample site;
- communicating the vacuum to the needle 36 (see figs. 1-2);
- probing the specimen sample site with the needle 36 to collect specimens in the collection well of the hub;
- releasing the vacuum in the needle 36;
- withdrawing the needle 36 from the specimen sample site;
- separating the hub from the device; and
- transferring specimens collected in the hub to an examination site (see figs. 1-2) column 4/lines 23-28, 37-43 & 59-64).

In regards to claim 56, Markham discloses a method of needle aspiration biopsy wherein the step of creating a vacuum in the syringe 10 includes closing the valve 28 and pulling the syringe piston 22 away from the syringe barrel 12 (see column 4/lines 23-28).

In regards to claim 57, Markham discloses a method of needle aspiration biopsy wherein the vacuum is communicated to the needle 36 by opening the valve 28 (see column 4/lines 37-43).

In regards to claim 58, Markham discloses a method of needle aspiration biopsy wherein the step of releasing the vacuum in the needle 36 includes reclosing the valve 28 (see column 4/lines 59-64).

DeVries as modified by Dann et al. disclose a system, as described above, that teaches all the limitations of the claims except DeVries as modified by Dann et al. do not teach a valve for controlling an opening in the syringe barrel. However, Markham disclose a valve 28 for controlling an opening in a syringe barrel 63 and a coupler 34 (see figs. 1-2). Since DeVries teaches an O-ring and a port 72 that act as a valve to release and create the vacuum in the system (see DeVries, column 1/lines 55-62; column 2/lines 3-12; column 3/lines 1-3 & 8-14), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Dann et al. with a stopcock valve similar to that of Markham in order to control the flow of fluid to the syringe barrel as is well known in the art (see Markham, figs. 1-2).

11. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Dann et al. ('075) further in view of Markham ('554) even further in view of Dysarz (US Patent No. 6,589,209).

DeVries as modified by Dann et al. and Markham disclose a system, as described above, that teaches all the limitations of the claims except DeVries as

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modified by Dann et al. and Markham does not teach a passageway that is defined in part by a needle and an internal channel in the hub. However, Dysarz discloses a system as follows:

However, Dysarz discloses a system wherein a passageway is defined in part by the needle 39 and in part by an internal channel 20 in the hub 48 (see figs. 1 & 18-19).

It would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Dann et al. and Markham with a passageway similar to that of Dysarz since such a modification would serve the same purpose of drawing a specimen into the collection well. It has previously been held that merely changing aesthetic design is not patentable--See *In re Seid*, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

12. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Dann et al. ('075) further in view of Markham ('554) even further in view of Elligson et al. ('556).

DeVries as modified by Dann et al. and Markham disclose a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except for a coupler. However, Elligson et al. disclose a system comprising a coupler 23 (see figs. 1-3B). It would have been obvious to one of ordinary skill in the art the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Dann et al. and Markham with a coupler similar to that of Elligson et al. in order to selectively connect establish a fluid communication between the hub and the syringe.

13. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Dann et al. ('075) further in view of Markham ('554) even further in view of Banys et al. ('376).

In regards to claim 54, DeVries as modified by Dann et al. and Markham disclose a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except DeVries as modified by Dann et al. and Markham do not teach a piston lock. However, Banys et al. teach a piston lock 42 mounted to the syringe so as to hold the position of the piston relative to the barrel (see figs. 5-6). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a biopsy device similar to that of DeVries as modified by Dann et al. and Markham with a piston lock similar to that of Banys et al. in order to hold the plunger in the fully inserted position within the syringe (see column 2/lines 63-65; column 4/lines 34-38).

14. Claims 40-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries (US Patent No. 4,967,762) in view of Guerra (US Patent No. 3,753,432).

In regards to claims 40 and 47-49, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device comprising:

a hub 40 defining a specimen collection well 62 and mounting a needle 70 having a shaft with an open pointed tip; and

a sample passageway 64 extending from the pointed tip of the needle 70 to a segment inside the hub opening in spaced relation to a floor of the collection well 62 (see figs. 1-2); DeVries discloses a high specimen yield anti-reflux head for a needle

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aspiration biopsy device wherein the hub 40 defines an opening 64 in the floor of the collection well 62 through which the needle shaft extends (see fig. 2); DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the proximal end of the needle 70 in part follows the contour of the collection well 62 (see fig. 2); DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the hub 40 includes an outer grip 52 (see figs. 1-2); DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the hub 40 has an open mouth 50 allowing access to the collection well 62 (see fig. 2).

In regards to claim 41, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the needle 70 defines the entire passageway 64 extending from the pointed tip to a contoured proximal end (see fig. 2).

In regards to claim 43, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the passageway 64 is defined in part by the needle 70 and in part by an internal channel in the hub 40 (see fig. 2).

In regards to claim 44, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the needle 70 has a straight proximal end disposed at an opening in the hub 40 defining an end of the channel (see fig. 2).

DeVries discloses an apparatus, as described above, that teaches all the limitations of the claims except DeVries does not teach a specimen passageway wherein a specimen can pass through the needle into the hub and be deposited in the collection well from above the floor. However, Guerra disclose an apparatus comprising

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a specimen passageway wherein a specimen can pass through the needle 18B and be deposited in the collection well 19 from above the floor; wherein the internal passage does not pass the collection well floor; Guerra further discloses a needle aspiration device wherein the proximal end of the needle includes a segment that extends along and opens about a lateral axis at an angle to a longitudinal axis of the needle; wherein the lateral and longitudinal axes are essentially perpendicular (see figs. 1-2). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an apparatus similar to that of DeVries with a specimen passageway similar to that of Guerra since such a modification would serve the same purpose of drawing a specimen into the collection well (see Guerra, column 3/lines 16-40).

Moreover, It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a needle aspiration device with a needle segment similar DeVries with a needle similar to that of Guerra in order to provide the needle with a safer connection that would resist slippage therefrom.

15. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries (US Patent No. 4,967,762) in view of Guerra (US Patent No. 3,753,432) further Dysarz (US Patent No. 6,589,209).

DeVries as modified by Guerra disclose a system, as described above, that teaches all the limitations of the claims except for a passageway that is defined in part by a needle and an internal channel in the hub. However, Dysarz discloses a system as follows:

However, Dysarz discloses a system wherein a passageway is defined in part by the needle 39 and in part by an internal channel 20 in the hub 48 (see figs. 1 & 18-19).

It would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Guerra with a passageway similar to that of Dysarz since such a modification would serve the same purpose of drawing a specimen into the collection well. It has previously been held that merely changing aesthetic design is not patentable--See *In re Seid*, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

16. Claims 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Guerra ('432) further in view of Ellingson et al. (US Patent No. 6,217,556).

In regards to claim 50, DeVries as modified by Guerra disclose a high specimen yielding anti-reflux needle aspiration biopsy device, comprising:

- a syringe including a barrel 20 and a piston 34 slidable within the barrel 20;
- a hub 40 and defining a specimen collection well 62; and
- a needle 70 mounted to the hub 40 having a shaft with an open pointed tip;

wherein at least one hub 40 and needle 70 define a passageway 64 extending from the needle tip to inside the hub opening to a floor of the collection well 62 (see DeVries, figs. 1-2).

In regards to claim 51, DeVries as modified by Guerra disclose a high specimen yielding anti-reflux needle aspiration biopsy device wherein the needle 70 defines the

entire passageway extending from the pointed tip to a contoured proximal end (see figs. 1-2).

DeVries as modified by Guerra disclose a system, as described above, that teaches all the limitations of the claims except DeVries as modified by Guerra do not teach a valve for controlling an opening in the syringe barrel. However, Ellingson et al. disclose a valve 23 for controlling an opening in a syringe barrel 63 (see fig. 1) and a coupler 35 (see fig. 3A). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that a valve to that of DeVries as modified by Guerra with a valve similar to that of Ellingson et al. in order to control the flow of fluid (see Ellingson et al., column 3/lines 17-22).

17. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Guerra ('432) further in view of Ellingson et al. ('556) even further in view of Dysarz (US Patent No. 6,589,209).

DeVries as modified by Guerra and Ellingson et al. disclose a system, as described above, that teaches all the limitations of the claims except DeVries as modified by Guerra and Ellingson et al. does not teach a passageway that is defined in part by a needle and an internal channel in the hub. However, Dysarz discloses a system as follows:

However, Dysarz discloses a system wherein a passageway is defined in part by the needle 39 and in part by an internal channel 20 in the hub 48 (see figs. 1 & 18-19).

It would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by

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Guerra and Ellingson et al. with a passageway similar to that of Dysarz since such a modification would serve the same purpose of drawing a specimen into the collection well. It has previously been held that merely changing aesthetic design is not patentable--See *In re Seid*, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

18. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Guerra ('432) further in view of Ellingson et al. ('556) even further in view of Banys et al. ('376).

In regards to claim 54, DeVries as modified by Guerra and Ellingson et al. disclose a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except DeVries as modified by Guerra and Ellingson et al. do not teach a piston lock. However, Banys et al. teach a piston lock 42 mounted to the syringe so as to hold the position of the piston relative to the barrel (see figs. 5-6). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a biopsy device similar to that of DeVries as modified by Guerra and Ellingson et al. with a piston lock similar to that of Banys et al. in order to hold the plunger in the fully inserted position within the syringe (see column 2/lines 63-65; column 4/lines 34-38).

19. Claims 50-51, and 55-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Guerra ('432) further in view of Markham (US Patent No. 4,549,554).

In regards to claim 50, DeVries as modified by Guerra disclose a high specimen yielding anti-reflux needle aspiration biopsy device, comprising:

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a syringe including a barrel 20 and a piston 34 slidable within the barrel 20;
a hub 40 and defining a specimen collection well 62; and
a needle 70 mounted to the hub 40 having a shaft with an open pointed tip;
wherein at least one hub 40 and needle 70 define a passageway 64 extending from the needle tip to inside the hub opening to a floor of the collection well 62 (see DeVries, figs. 1-2).

In regards to claim 51, DeVries as modified by Guerra disclose a high specimen yielding anti-reflux needle aspiration biopsy device wherein the needle 70 defines the entire passageway extending from the pointed tip to a contoured proximal end (see figs. 1-2).

In regards to claim 55, DeVries as modified by Guerra discloses a method as follows:

inserting the needle 70 into a specimen sample site;
communicating a vacuum to the needle 70;
probing the specimen sample site with the needle 70 to collect specimens in the collection well of the hub 40;
releasing the vacuum in the needle 70;
withdrawing the needle 70 from the specimen sample site;
separating the hub from the device; and
transferring specimens collected in the hub to an examination site (see DeVries, column 1/lines 55-72; column 2/lines 3-12; column 3/lines 1-3 & 8-14).

DeVries as modified by Guerra teach a system, as described above, that teaches all the limitations of the claims except DeVries as modified by Guerra does not teach creating a vacuum by closing a valve and pulling a piston. However, Markham teaches a method as follows:

In regards to claim 55, Markham discloses a method of needle aspiration biopsy using a device as recited in claim 50, comprising the steps of:

- creating a vacuum in the syringe 10;
- inserting the needle 36 into a specimen sample site;
- communicating the vacuum to the needle 36 (see figs. 1-2);
- probing the specimen sample site with the needle 36 to collect specimens in the collection well of the hub;
- releasing the vacuum in the needle 36;
- withdrawing the needle 36 from the specimen sample site;
- separating the hub from the device; and
- transferring specimens collected in the hub to an examination site (see figs. 1-2) column 4/lines 23-28, 37-43 & 59-64).

In regards to claim 56, Markham discloses a method of needle aspiration biopsy wherein the step of creating a vacuum in the syringe 10 includes closing the valve 28 and pulling the syringe piston 22 away from the syringe barrel 12 (see column 4/lines 23-28).

In regards to claim 57, Markham discloses a method of needle aspiration biopsy wherein the vacuum is communicated to the needle 36 by opening the valve 28 (see column 4/lines 37-43).

In regards to claim 58, Markham discloses a method of needle aspiration biopsy wherein the step of releasing the vacuum in the needle 36 includes reclosing the valve 28 (see column 4/lines 59-64).

DeVries as modified by Guerra disclose a system, as described above, that teaches all the limitations of the claims except DeVries as modified by Guerra do not teach a valve for controlling an opening in the syringe barrel. However, Markham disclose a valve 28 for controlling an opening in a syringe barrel 63 and a coupler 34 (see figs. 1-2). Since DeVries teaches an O-ring and a port 72 that act as a valve to release and create the vacuum in the system (see DeVries, column 1/lines 55-62; column 2/lines 3-12; column 3/lines 1-3 & 8-14), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Guerra with a stopcock valve similar to that of Markham in order to control the flow of fluid to the syringe barrel as is well known in the art (see Markham, figs. 1-2).

20. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Guerra ('432) further in view of Markham ('554) even further in view of Dysarz (US Patent No. 6,589,209).

DeVries as modified by Guerra and Markham disclose a system, as described above, that teaches all the limitations of the claims except DeVries as modified by

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Guerra and Markham does not teach a passageway that is defined in part by a needle and an internal channel in the hub. However, Dysarz discloses a system as follows:

However, Dysarz discloses a system wherein a passageway is defined in part by the needle 39 and in part by an internal channel 20 in the hub 48 (see figs. 1 & 18-19).

It would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Guerra and Markham with a passageway similar to that of Dysarz since such a modification would serve the same purpose of drawing a specimen into the collection well. Moreover, it has previously been held that merely changing aesthetic design is not patentable--See *In re Seid*, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

21. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Guerra ('432) further in view of Markham ('554) even further in view of Ellingson et al. ('556).

DeVries as modified by Guerra and Markham disclose a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except for a coupler. However, Ellingson et al. disclose a system comprising a coupler 23 (see figs. 1-3B). It would have been obvious to one of ordinary skill in the art the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Guerra and Markham with a coupler similar to that of Ellingson et al. in order to selectively connect establish a fluid communication between the hub and the syringe.

22. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Guerra ('432) further in view of Markham ('554) even further in view of Banys et al. ('376).

In regards to claim 54, DeVries as modified by Guerra and Markham disclose a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except DeVries as modified by Guerra and Markham do not teach a piston lock. However, Banys et al. teach a piston lock 42 mounted to the syringe so as to hold the position of the piston relative to the barrel (see figs. 5-6). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a biopsy device similar to that of DeVries as modified by Guerra and Markham with a piston lock similar to that of Banys et al. in order to hold the plunger in the fully inserted position within the syringe (see column 2/lines 63-65; column 4/lines 34-38).

Response to Arguments

23. Applicant's arguments filed April 18, 2007 have been fully considered but they are not persuasive. Applicant argues that there is no motivation to combine the previously cited references because "under current standard for obviousness, there must be a motivation or suggestion in the references to make the combination."

In regards to the Applicant's argument, the Examiner respectfully disagrees. it is not required that the prior art disclose or suggest the properties newly-discovered by an applicant in order for there to be a prima facie case of obviousness. See *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897, 1905 (Fed. Cir. 1990). Moreover, as long as some

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motivation or suggestion to combine the references is provided by the prior art taken as a whole, the law does not require that the references be combined for the reasons contemplated by the inventor. See *In re Beattie*, 974 F.2d 1309, 24 USPQ2d 1040 (Fed. Cir. 1992); *In re Kronig*, 539 F.2d 1300, 190 USPQ 425 (CCPA 1976) and *In re Wilder*, 429 F.2d 447, 166 USPQ 545 (CCPA 1970).

Moreover, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F. 2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a conclusion of obviousness may be based on common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. *In re Bozek*, 416 F .2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969). As such, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Conclusion

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/RTT/



MAX F. HINDENBURG
SENIOR PATENT EXAMINER
TECHNOLOGY CENTER 3700